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Genetic Privacy

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Human genomic information is invested with enormous power in a scientifically motivated society. Genomic information has the capacity to produce a great deal of good for society. It can help identify and understand the etiology and pathophysiology of disease. In so doing, medicine and science can expand the ability to prevent and ameliorate human malady through genetic testing, treatment, and reproductive counseling.

Genomic information can just as powerfully serve less beneficent ends. Information can be used to discover deeply personal attributes of an individual's life. That information can be used to invade a person's private sphere, to alter a person's sense of self- and family identity, and to affect adversely opportunities in education, employment, and insurance.¹ Genomic information can also affect families and ethnic groups that share genetic similarities.

It is sometimes assumed that significant levels of privacy can coexist with widespread collection of genomic information. Understandably, we want to advance all valid interests—both collective and individual. We want to believe that we can continue to acquire and use voluminous data from the human genome while also protecting individual, family, and group privacy. This article demonstrates that no such easy resolution of the conflict between the need for genomic information and the need for privacy exists. Because absolute privacy cannot realistically be achieved while collecting genetic data, we confront a hard choice: Should we sharply limit the systematic collection of genomic information to achieve reasonable levels of privacy? Or, is the value of genomic information so important to the achievement of societal aspirations for health that the law ought not promise absolute or even significant

levels of privacy, but rather that data be collected and used in orderly and just ways, consistent with the values of individuals and communities? As I argue, the law at present neither adequately protects privacy nor ensures fair information practices. Moreover, the substantial variability in the law probably impedes the development of an effective genetic information system.

In earlier articles, I scrutinized the meaning and boundaries of health information privacy.² Here, I build on that work by examining a particular aspect of health information—genetic privacy. I acknowledge a debt to those scholars who have aptly identified and wrestled with the difficult ethical and legal issues inherent in genomic information.³ This is well-tread territory; what I hope to bring to the literature is a conceptual structure relating to the acquisition and use of genomic information. First, the methods of collection and use of genomic data must be understood and its public purposes evaluated. Second, the privacy implications of genomic information must be measured. To what extent are genomic data the same as, or different from, other health information? Third, an examination of the current constitutional and statutory law must be undertaken to determine whether existing safeguards are adequate to protect the privacy and security of genomic data. Finally, proposals for balancing societal needs for genomic information and claims for privacy by individuals and families must be generated.

Genetic information infrastructure

I define the *genetic information infrastructure* as the basic, underlying framework of collection, storage, use, and transmission of genomic information (including human tissue and extracted DNA) to support all essential functions in genetic research, diagnosis, treatment, and reproductive

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counseling. Despite the technical problems and the cost, several governmental⁴ and private⁵ committees have proposed automation of health data, including genomic information. Several conceptual and technological innovations are likely to accelerate the automation of health records: patient-based longitudinal clinical records, which include genetic testing and screening information; unique identifiers and the potential to link genomic information to identifiable persons; and genetic data bases for clinical, research, and public health purposes.

Longitudinal clinical records: testing and screening

The health care system is moving toward patient-based longitudinal health records. These records, held in electronic form, contain all data relevant to the individual's health collected over a lifetime. What is foreseen is a single record for every person in the United States, continually expanded from prebirth to death, and accessible to a wide range of individuals and institutions.⁶

Genetic testing and screening are likely to become an important part of longitudinal clinical records. The principal forms include: fetal (prenatal), newborn, carrier, and clinical (primary care) screening.⁷ Prenatal screening seeks to identify disease in the fetus. Prenatal diagnosis of birth defects often involves genetic analysis of amniotic fluid, blood, or other tissues. Prenatal diagnostic methods are used for genetic diseases including Down syndrome, Tay-Sachs, sickle cell, and thalassemia major (Cooley's anemia). Newborn screening often focuses on detection of inborn errors of metabolism. Phenylketonuria (PKU) was the first condition subject to newborn screening; other inborn defects often screened at birth are galactosemia, branched-chain ketonuria, and homocystinuria.⁸ Carrier screening seeks to identify heterozygotes for genes for recessive disease. Carrier testing has been used for such conditions as Tay-Sachs, cystic fibrosis (CF), and sickle cell.

The Human Genome Initiative has advanced to the point where it is now possible to conceive of an ever-expanding ability to detect genetic causes of diseases in individuals and populations. Testing for predispositions to disease represents one of the most important developments. For example, testing for predispositions to Huntington's disease, colon cancer, heart disease, and Alzheimer's disease are currently possible or expected.⁹ Relatively recent discoveries include genes found for ataxia-telangiectasia (a rare hereditary neurological disorder of childhood),¹⁰ Lowe syndrome (a rare X-linked disorder affecting diverse organ systems),¹¹ melanoma, pancreatic cancer,¹² and breast cancer.¹³ Genetic methods to identify elevated risk for multifactorial diseases are also likely. It may be possible, for example, to identify individuals at risk for such conditions as schizophrenia, manic depression, and alcohol or drug dependency.

Clinical records could potentially be linked to many other sources of genomic information: (i) a lucrative commercial market in self-testing, which is growing even before scientists regard test-kits as reliable (for example, testing for genetic predictors of breast cancer);¹⁴ (ii) workplace screening, through which employers can determine an employee's current and future capacity to perform a job or to burden pension or health care benefit plans¹⁵ (such testing may occur despite some legal restrictions under disability discrimination statutes¹⁶); (iii) screening to determine eligibility for health, life, and disability insurance, which is likely when tests are more cost-effective;¹⁷ (iv) testing in the criminal justice system, which will increase as more courts recognize the probative value of genomic data;¹⁸ and (v) testing for a wide variety of public purposes (for instance, to prevent fraud in collection of welfare or other social benefits, to identify family ties in adoption, and to adjudicate paternity suits).¹⁹ Automated health information systems hold the capacity electronically to link information collected for these and other purposes. Data from several sources can be compared and matched; and different configurations of data can reveal new understandings about the individual.

It is thus possible to conceive of a genetic information system that contains a robust account of the past, present, and future health of each individual, ranging from genetic fetal abnormalities and neonate carrier states, to current and future genetic conditions at different points in one's life. Genetic data can even explain causes of morbidity and mortality after death; for example, genetic technologies were used to determine whether Abraham Lincoln had Marfan's disease.²⁰ As will become apparent below, such genetic explanations of morbidity and mortality provide an expansive understanding of the attributes not only of the individual, but also of her family (ancestors as well as current and future generations) and possibly of whole populations.

Unique identifiers and potential links to identifiable persons

Health data can be collected and stored in identifiable or nonidentifiable forms. Data raise different levels of privacy concerns, depending on whether they can be linked to a specific person. The most serious privacy concerns are raised where genomic data are directly linked to a known individual. For reasons of efficiency, many health plans in the private and public sector are considering the use of unique identifiers. These identifiers would be used for a variety of health, administrative, financial, statistical, and research purposes. The identifier would facilitate access to care and reimbursement for services rendered. Some envisage using the social security number (SSN) as the unique identifier, which is controversial because the SSN is linked

to data from the Internal Revenue Service, Department of Defense, debt collectors, the Medical Information Bureau, credit care companies, and so forth.

Where data are collected or held in nonidentifiable form, they pose few problems of privacy. Because anonymous data are not personally linked, they cannot reveal intimate information that affect individual privacy rights. Epidemiological data, including health statistics, are frequently collected in this form. This enables investigators or public health personnel to collect a great deal of information, usually without measurable burdens on privacy interests. The obvious question arises whether genomic data can also be collected in nonidentifiable form. Genomic data that are not linked to identified individuals can significantly reduce, but do not eliminate, privacy concerns. Genomic data are qualitatively different from other health data because they are inherently linked to one person. While non-genetic descriptions of any given patient's disease and treatment could apply to many other individuals, genomic data are unique. But, although the ability to identify a named individual in a large population simply from genetic material is unlikely, the capacity of computers to search multiple data bases provides a potential for linking genomic information to that person. It follows that nonlinked genomic data do not assure anonymity and that privacy and security safeguards must attach to any form of genetic material. It is, therefore, a concern that even the strict genetic privacy statutes that have been introduced in Congress exempt "personal genetic records maintained anonymously for research purposes only."²¹ Minimally, such statutes must require that privacy and security arrangements ensure that these "anonymous" data are never linked to identified persons.

Genetic data bases

Data bases collect, store, use, and transfer vast amounts of health information, often in electronic or automated form. The technology exists to transfer data among data bases, to match and reconfigure information, and to seek identifying characteristics of individuals and populations. Data bases hold information on numerous subjects including medical cost reimbursements, hospital discharges, health status, research, and specific diseases.²² A growing number of data bases also contain genetic information.²³ Genetic research usually requires only DNA, sources of which include not only solid tissues, but also blood, saliva, and any other nucleated cells.²⁴ Reilly defines DNA banking as "the long-term storage of cells, transformed cell lines, or extracted DNA for subsequent retrieval and analysis"; it is "the indefinite storage of information derived from DNA analysis, such as linkage profiles of persons at risk for Huntington Disease or identity profiles based on analysis with a set of probes and enzymes."²⁵

Genetic data bases are held in both the private and public sector for clinical, research, and public health purposes. The National Institutes of Health (NIH), for example, maintains a genetic data base for cancer research, while private universities, such as the University of Utah human tissue repository, conduct genetic research. Commercial companies offer genetic banking as a service to researchers or individuals.²⁶ Genetic data bases are also created to support nonhealth-related functions, such as identification of the remains of soldiers,²⁷ detection, prosecution, and post-conviction supervision through "DNA fingerprinting" of persons engaging in criminal conduct,²⁸ and identification of blood lines in paternity and child disputes.²⁹

One problematic source of information is previously stored tissue samples. Stored samples may be regarded as inchoate data bases because the technology exists to extract from them considerable current and future health data.³⁰ The public health and research communities have shown increasing interest in using existing tissue samples for genetic testing and for creating new genetic data bases. From a privacy perspective, this interest raises a serious problem: any consent that was obtained when that tissue was originally extracted would not meet current informed consent standards because the donor could not have envisaged future genetic applications.

The most prominent example of an inchoate genetic data base is the Guthrie spot program, whereby dried blood spots are taken from virtually all newborns throughout the United States. All states screen newborns for PKU, congenital hyperthyroidism, and other genetic defects. The genetic composition of Guthrie spots remains stable for many years and, if frozen, can be held indefinitely. A recent survey found that three-quarters of the states store their Guthrie cards, with thirteen storing them for more than five years. Of them, several store these cards indefinitely; and a number of other states have expressed an intention to do so.³¹ Only two require parental consent for the blood spot.

Perhaps the most ambitious public or private effort to create a data base with both genetic and nongenetic applications is the National Health and Nutrition Examination Survey (NHANES) conducted by several federal agencies.³² NHANES has collected comprehensive health status data in patient-identifiable form on some 40,000 Americans in eighty-one counties in twenty-six states. About 500 pieces of data are collected from each subject, ranging from socio-demographics, diet, bone density, and blood pressure, to risk status, drug use, and sexually transmitted diseases (STDs). Additionally, NHANES tests and stores biological samples for long-term follow-up and statistical research.

NHANES provides a classic illustration of a massive collection of highly personal and sensitive information that has enduring societal importance. These data pose a significant risk of privacy invasion, but they are critical to understanding health problems in the population.

Clinical and public health benefits of genomic information

Americans seem enamored with the power of genomic information. It is often thought capable of explaining much that is human: personality, intelligence, appearance, behavior, and health.³³ Genetic technologies generated from scientific assessment are commonly believed always to be accurate and highly predictive. These beliefs are highly exaggerated; for instance, personal attributes are influenced by social, behavioral, and environmental factors.

A person's genetic diary, moreover, is highly complex, with infinite possibilities of genetic influence. Ample evidence exists that the results of genetic-based diagnosis and prognosis are uncertain. The sensitivity of genetic testing is limited by the known mutations in a target population. For example, screening can detect only 75 percent of CF chromosomes in the U.S. population. Approximately one of every two couples from the general population identified by CF screening as "at-risk" will be falsely labeled.³⁴ Predicting the nature, severity, and course of disease based on a genetic marker is an additional difficulty. For most genetic diseases, the onset date, severity of symptoms, and efficacy of treatment and management vary greatly.

Nonetheless, the force of genomic information, even if exaggerated, is powerful. Genomic information is highly beneficial for health care decisions regarding prevention, treatment, diet, lifestyle, and reproductive choices. In particular, collection of genomic data can provide the following benefits to individuals and to society.

Enhanced patient choice. Genetic testing can enhance autonomous decision making by providing patients with better information. Genomic data, for example, can provide information about carrier states, enabling couples to make more informed reproductive choices; about disabilities of the fetus, guiding decisions about abortion or fetal treatment; about markers for future disease, informing lifestyle decisions; and about current health status, providing greater options for early treatment. Some may not agree that genetic information used for these purposes is inherently good, for the information could be used to increase selective abortion to "prevent" the births of babies with genetic disabilities.

Clinical benefit. Often a disconnection exists between the ability of science to detect disease and its ability to prevent, treat, or cure it. Scientific achievement in identifying genetic causes of disease must be tempered by a hard look at scientifically possible methods of intervention. As discussed below, if the possible stigma or discrimination associated with the disease is great, and science remains powerless to prevent or treat it, the potential benefits may outweigh harms. Despite this caveat, the Human Genome Initiative holds the current or potential ability to achieve a great deal of good for patients.

Couples can decide to change their plans for repro-

duction based on information disclosed in genetic counseling, thus reducing the chance of a child born with disease. Detection of metabolic abnormalities can empower a person to control their diet and lifestyle to prevent the onset of symptomatology. Identification of enhanced risk for multifactorial diseases, such as certain cancers or mental illness, could help people avoid exposure to particular occupational or environmental toxins or stresses.³⁵ Finally, medicine is increasing its ability to treat genetic conditions. Wivel and Walters discuss several categories of human genetic intervention: somatic cell gene therapy involving correction of genetic defects in any human cells except germ or reproductive cells; germ-line modification involving correction or prevention of genetic deficiencies through the transfer of properly functioning genes into reproductive cells; and use of somatic and/or germ-line modifications to effect selected physical and mental characteristics, with the aim of influencing such features as physical appearance or physical abilities (in the patient or in succeeding generations).³⁶ While use of germ-line therapy, particularly when designed to enhance human capability, is highly charged, most people agree that the ability to prevent and treat genetic disease offers patients a chance for health and well-being that would not be possible absent genetic intervention. Clinical applications of genetic technologies are also possible in other areas; for example, scientists have reported progress in transplanting animal organs into humans. Insertion of human genes into animals could render their organs more suitable for transplantation into humans without substantial tissue rejection.³⁷

Improved research. Despite substantial progress in the Human Genome Initiative, a great deal more must be understood about the detection, prevention, and treatment of genetic disease. Genetic research holds the potential for improving diagnosis, counseling, and treatment for persons with genetic conditions or traits. Research can help determine the frequency and distribution of genetic traits in various populations, the interconnections between genotypes and phenotypes, and the safety and efficacy of various genetic interventions.

Genetic data bases, containing DNA and/or stored tissue, could make this kind of research less expensive by reducing the costs of collecting and analyzing data, more trustworthy by increasing the accuracy of the data, and more generalizable to segments of the population by assuring the completeness of the data.

Protection of public health. While traditional genetic diagnosis, treatment, and research is oriented toward the individual patient, genetic applications can also benefit the public health. There is considerable utility in using population-based data to promote community health. Genomic data can help track the incidence, patterns, and trends of genetic carrier states or disease in populations. Carefully planned surveillance or epidemiological activities facilitate

rapid identification of health needs. This permits reproductive counseling, testing, health education, and treatment resources to be better targeted, and points the way for future research. For example, recent epidemiological research of DNA samples from Eastern European Jewish women found that nearly 1 percent contained a specific gene mutation that may predispose them to breast and ovarian cancer. This finding offered the first evidence from a large study that an alteration in the gene, BRCA1, is present at measurable levels not only in families at high risk for disease, but also in a specific group of the general population.³⁸ Certainly, evidence of enhanced risk of disease in certain populations, such as sickle cell in African Americans or Tay-Sachs in Ashkenazi Jews, may foster discrimination against these groups. At the same time, population-based genetic findings support other clinical studies to evaluate the risk to populations bearing the mutation or to determine whether BRCA1 testing should be offered to particular ethnic groups as part of their routine health care.

Privacy implications of genomic data

The vision of a comprehensive genetic information system described above is technologically feasible, and a well-functioning system would likely achieve significant benefits for individuals, families, and populations. However, to decide whether to continue to accumulate vast amounts of genomic information, it is necessary to measure the probable effects on the privacy of these groups. The diminution in privacy entailed in genetic information systems depends on the sensitive nature of the data, as well as on the safeguards against unauthorized disclosure of the information.

Genomic data and harms of disclosure

Privacy is not simply the almost inexhaustible opportunities for access to data; it is also the intimate nature of those data and the potential harm to persons whose privacy is violated.³⁹ Health records contain much information with multiple uses: demographic information; financial information; information about disabilities, special needs, and other eligibility criteria for government benefits; and medical information. This information is frequently sufficient to provide a detailed profile of the individual and that person's family. Traditional medical records, moreover, are only a subset of records containing personal information held by social services, immigration, and law enforcement.

Genomic data can personally identify an individual and his/her parents, siblings, and children, and provide a current and future health profile with far more scientific accuracy than other health data. The features of a person revealed by genetic information are fixed—unchanging and unchangeable. Although some genomic data contain infor-

mation that is presently indecipherable, they may be unlocked by new scientific understanding; but such discoveries could raise questions about improper usage of stored DNA samples.⁴⁰ Finally, societies have previously sought to control the gene pool through eugenics. This practice is particularly worrisome because different genetic characteristics occur with different frequencies in racial and ethnic populations.

The combination of emerging computer and genetic technologies poses particularly compelling privacy concerns. Scientists have the capacity to store a million DNA fragments on one silicon microchip.⁴¹ While this technology can markedly facilitate research, screening, and treatment of genetic conditions, it may also permit a significant reduction in privacy through its capacity to store and decipher unimaginable quantities of highly sensitive data.

A variety of underlying harms to patients may result from unwanted disclosures of these sensitive genomic data. A breach of privacy can result in economic harms, such as loss of employment, insurance, or housing. It can also result in social or psychological harms. Disclosure of some conditions can be stigmatizing, and can cause embarrassment, social isolation, and a loss of self-esteem. These risks are especially great when the perceived causes of the health condition include drug or alcohol dependency, mental illness, mental retardation, obesity, or other genetically linked conditions revealed by a person's DNA. Even though genomic information can be unreliable or extraordinarily complicated to decipher, particularly with multifactorial disease or other complicated personal characteristics (for instance, intelligence), public perceptions attribute great weight to genetic findings and simply aggravate the potential stigma and discrimination.

Maintaining reasonable levels of privacy is essential to the effective functioning of the health and public health systems. Patients are less likely to divulge sensitive information to health professionals, such as family histories, if they are not assured that their confidences will be respected. The consequence of incomplete information is that patients may not receive adequate diagnosis and treatment. Persons at risk of genetic disease may not come forward for the testing, counseling, or treatment. Informational privacy, therefore, not only protects patients' social and economic interests, but also their health and the health of their families and discrete populations.

Legal protection of genetic privacy and security of health information

One method of affording some measure of privacy protection is to furnish rigorous legal safeguards. Current legal safeguards are inadequate, fragmented, and inconsistent, and contain major gaps in coverage. Significant theoretical problems also exist.

Constitutional right to privacy

A considerable literature has emerged on the existence and extent of a constitutional right to informational privacy independent of the Fourth Amendment prohibition on unreasonable searches and seizures.⁴² To some, judicial recognition of a constitutional right to informational privacy is particularly important because the government is an important collector and disseminator of information. Citizens, it is argued, should not have to rely on government to protect their privacy interests. Rather, individuals need protection from government itself, and an effective constitutional remedy is the surest method to prevent unauthorized government acquisition or disclosure of personal information. The problem with this approach is that the Constitution does not expressly provide a right to privacy, and the Supreme Court has curtailed constitutional protection both for decisional and informational privacy.⁴³

Notwithstanding the Court's current retreat, a body of case law does suggest judicial recognition of a limited right to informational privacy as a liberty interest within the Fifth and Fourteenth Amendments to the Constitution. In *Whalen v. Roe*,⁴⁴ the Supreme Court squarely faced the question of whether the constitutional right to privacy encompasses the collection, storage, and dissemination of health information in government data banks. In *dicta*, the Court acknowledged "the threat to privacy implicit in the accumulation of vast amounts of personal information in computerized data banks or other massive government files."⁴⁵ However, the Court hardly crafted an adequate constitutional remedy to meet this threat. Justice Stevens, writing for a unanimous court, simply recognized that "in some circumstances" the duty to avoid unwarranted disclosures "arguably has its roots in the Constitution."⁴⁶ The Court found no violation in *Whalen* because the state had adequate standards and procedures for protecting the privacy of sensitive medical information. Rather, it suggested deferentially that supervision of public health and other important government activities "require[s] the orderly preservation of great quantities of information, much of which is personal in character and potentially embarrassing or harmful if disclosed."⁴⁷

Most lower courts have read *Whalen* as affording a circumscribed right to informational privacy, or have grounded the right on state constitutional provisions.⁴⁸ Courts have employed a flexible test balancing the government invasion of privacy and the strength of the government interest. For example, the Third Circuit in *United States v. Westinghouse Electric Corp.*⁴⁹ enunciated five factors to be balanced in determining the scope of the constitutional right to informational privacy: (1) the type of record and the information it contains; (2) the potential for harm in any unauthorized disclosure; (3) the injury from disclosure to the relationship in which the record was generated; (4) the adequacy of safeguards to prevent nonconsensual

disclosure; and (5) the degree of need for access—that is, a recognizable public interest.

Judicial deference to government's expressed need to acquire and use information is an unmistakable theme in the case law. Provided that government articulates a valid societal purpose and employs reasonable security measures, courts have not interfered with traditional governmental activities of information collection. Unmistakably, government could enunciate a powerful societal purpose in the collection of genomic information such as public health or law enforcement.

The right to privacy under the Constitution is, of course, limited to state action. As long as the federal or a state government itself collects information or requires other entities to collect it, state action will not be a central obstacle. However, collection and use of genomic data by private or quasi-private health data organizations, health plans, researchers, and insurers remains unprotected by the Constitution, particularly in light of an absence of government regulation of genetic data banking.

Legislating health information privacy: theoretical concerns

Legislatures and agencies have designed a number of statutes and regulations to protect privacy. A full description and analysis of the legislation and regulation is undertaken elsewhere.⁵⁰ The Department of Health and Human Services described this body of legislation as "a morass of erratic law."⁵¹ The law is fragmented, highly variable, and, at times, weak; the legislation treats some kinds of data as super-confidential, while providing virtually no protection for other kinds.

Health data are frequently protected as part of the physician-patient relationship. However, data collected in our information age is based only in small part on this relationship. Many therapeutic encounters in a managed care context are not with a primary care physician. Patients may see various nonphysician health professionals. Focusing legal protection on a single therapeutic relationship within this information environment is an anachronistic vestige of an earlier and simpler time in medicine. Moreover, the health record, as I pointed out, contains a substantial amount of information gathered from numerous primary and secondary sources. Patients' health records not only are kept in the office of a private physician or of a health plan, but also are kept by government agencies, regional health data base organizations, or information brokers. Data bases maintained in each of these settings will be collected and transmitted electronically, reconfigured, and linked.

Rules enforcing informational privacy in health care place a duty on the entity that possesses the information. Thus, the keeper of the record—whether a private physician's office, a hospital, or a hospital maintenance organi-

zation—holds the primary duty to maintain the confidentiality of the data. The development of electronic health care networks permitting standardized patient-based information to flow nationwide, and perhaps worldwide, means that the current privacy protection system, which focuses on requiring the institution to protect its records, needs to be reconsidered. Our past thinking assumed a paper or automated record created and protected by the provider. We must now envision a patient-based record that anyone in the system can call up on a screen. Because location has less meaning in an electronic world, protecting privacy requires attaching protection to the health record itself, rather than to the institution that generates it.

Genetic privacy legislation

A genetic-specific privacy statute has been introduced in Congress.⁵² Several states have adopted genetic-specific privacy laws,⁵³ and others have bills pending.⁵⁴ Eight states have provisions that prohibit obtaining and/or disclosing genomic information about individuals without their informed consent; one of these is limited to information about sickle cell testing.⁵⁵ These genetic privacy statutes are highly variable. While a few, such as California's Hereditary Disorders Act, provide privacy protection across a broad range of genomic information, most statutes have limited application. For example, privacy statutes in Maine, Massachusetts, Missouri, Ohio, Tennessee, and Virginia are applicable principally to genetic screening programs conducted by or under the auspices of the state health department. They may leave the private sector virtually unregulated in its collection and use of genomic data. Other states, like Florida, have strong, generally applicable, provisions giving persons "exclusive property" rights over genomic information, but specify broad exemptions for data collected for criminal prosecutions and determinations of paternity.

Additional statutes protect the confidentiality of genomic information, but do so with narrow purpose. Several states regulate the use of genomic data collected for insurance underwriting⁵⁶ or determinations of parentage.⁵⁷ Among the eight states that proscribe genetic discrimination in insurance, most simply require actuarial fairness and a few require confidentiality; the actuarial provisions have the effect of promoting accuracy, but little more. In Nevada, the genetic privacy statute applies only to the state university system.⁵⁸

The adoption of a genetic-specific privacy statute at the federal or state level has been proposed.⁵⁹ A recently drafted model federal act incorporates traditional fair information practices into the collection and use of genomic data.⁶⁰ Under this model act, a person who collects human tissue for the purposes of genetic analysis must provide specific information and a notice of rights prior to collection; obtain written authorization; restrict access to DNA

samples; and abide by a sample source's instructions regarding the maintenance and destruction of DNA samples.

Existing and proposed genetic-specific privacy statutes are founded on the premise that genetic information is sufficiently different from other health information to justify special treatment. Certainly, genomic data present compelling justifications for privacy protection: the sheer breath of information discoverable; the potential to unlock secrets that are currently unknown about the person; the unique quality of the information enabling certain identification of the individual; the stability of DNA rendering distant future applications possible; and the generalizability of the data to families, genetically related communities, and ethnic and racial populations.

It must also be observed that genetic-specific privacy statutes could create inconsistencies in the rules governing dissemination of health information. Under genetic-specific privacy statutes, different standards would apply to data held by the same entity, depending on whether genetic analysis had been used. The creation of strict genetic-specific standards may significantly restrain the dissemination of genomic data (even to the point of undermining legitimate health goals), while nongenomic data receive insufficient protection. Arguments that genomic data deserve special protection must reckon with the fact that other health conditions raise similar sensitivity issues (for examples, HIV infection, tuberculosis, STDs, and mental illnesses). Indeed, carving out special legal protection for sensitive data may be regarded as inherently faulty, because the desired scope of privacy encompassing a health condition varies from individual to individual. Some patients may be just as sensitive about prevalent nongenetic or multifactorial diseases like cancer and heart disease as they are about diseases with a unique genetic component. Even if it could be argued that most diseases will one day be found to be, at least in part, genetically caused, this will still raise questions about why purely viral or bacterial diseases should receive less, or different, protection.

Finally, adoption of different privacy and security rules for genomic data could pose practical problems in our health information infrastructure. The flow of medical information is rarely restricted to particular diseases or conditions. Transmission of electronic data for purposes of medical consultation, research, or public health is seldom limited to one kind of information. Requiring hospitals, research institutions, health departments, insurers, and others to maintain separate privacy and security standards (and perhaps separate record systems) for genomic data may not be wise or practical. A more thoughtful solution would be to adopt a comprehensive federal statute on health information privacy, with explicit language applying privacy and security standards to genomic information. If genomic data were insufficiently protected by these legal standards, additional safeguards could be enacted.

Uniform standards for acquisition and disclosure of health information

I previously proposed uniform national standards for the acquisition and disclosure of health information.⁶¹ Below, I briefly describe those standards and outline how they would apply equally to genomic data.⁶²

Substantive and procedural review. Many see the collection of health data as an inherent good. Even if the social good to be achieved is not immediately apparent, it is always possible that some future benefit could accrue. But despite optimism in the power of future technology, the diminution in privacy attributable to the collection of health data demands that the acquisition of information serve some substantial interest. The burden rests on the collector of information not merely to assert a substantial public interest, but also to demonstrate that it would be achieved. Information should only be collected under the following conditions: (1) the need for the information is substantial; (2) the collection of the data would actually achieve the objective; (3) the purpose could not be achieved without the collection of identifiable information; and (4) the data would be held only for a period necessary to meet the valid objectives. Thus, collectors of genomic information would have to justify the collection and to use of the information, and they would have to show why collection of tissue or DNA is necessary to achieve the purpose.

The collection of large amounts of health information, such as a tissue or a DNA repository, not only requires a substantive justification, but also warrants procedural review. Decisions to create health data bases, whether by government or private sector, ought to require procedural review. Some mechanism for independent review by a dispassionate expert body would provide a forum for examination of the justification for the data collection, the existence of thoughtful consent procedures, and the maintenance of adequate privacy and security.

Autonomy to control personal data. If a central ethical value behind privacy is respect for personal autonomy, then individuals from whom data are collected must be afforded the right to know about and to approve the uses of those data. Traditional informed consent requires that a competent person have adequate information to make a genuinely informed choice. However, few objective standards have been developed to measure the adequacy of consent. To render consent meaningful, the process must incorporate clear content areas:⁶³ how privacy and security will be maintained; the person's right of ownership of, and control over, the data; specific instructions on means of access, review, and correction of records; the length of time that the information will be stored and the circumstances when it would be expunged; authorized third-party access to the data; and future secondary uses. If secondary uses of those data go beyond the scope of the original consent (for example, use of human tissue to create cell lines or disclo-

sure to employers or insurers) additional consent must be sought.

Right to review and correct personal data. A central tenet of fair information practices is that individuals have the right to review data about themselves and to correct or amend inaccurate or incomplete records. This right respects a person's autonomy, while assuring the integrity of data. Individuals cannot meaningfully control the use of personal data unless they are fully aware of their contents and can assess the integrity of the information. Individuals can also help determine if the record is accurate and complete. Health data can only achieve essential societal purposes if they are correct and reasonably comprehensive. One method, therefore, of ensuring the reliability of health records is to provide a full and fair procedure to challenge the accuracy of records and to make corrections. Thus, persons must be fully aware of the tissue and genetic material that is collected and stored. Moreover, they must be fully informed about the *content* and *meaning* of any genetic analysis—past, current, or future. For instance, if an individual consents to the collection of tissue for epidemiological research on breast cancer, he/she would be entitled to see and correct any information derived from that tissue. If, in the future, the tissue were used to predict, say, dementia in the patient, he/she would have to consent and would also have the right to see and correct any new information derived from that particular genetic analysis.

Use of data for intended purposes. Entities that possess information have obligations that go beyond their own needs and interests. In some sense, they hold the information on behalf of the individual and, more generally, for the benefit of all patients in the health system. A confidence is reposed in a professional who possesses personal information for the benefit of others. They have an obligation to use health information only for limited purposes; to disclose information only for purposes for which the data were obtained; to curtail disclosure to the minimum necessary to accomplish the purpose; and to maintain an accounting of any disclosure.

The idea of seeing holders of information as trustees has special force with genomic data. Because DNA might unlock the most intimate secrets of human beings and holds the potential for unethical uses, those who possess it must meet the highest ethical standards.

Conclusion

The human genome retains enormous appeal in the United States. Americans, enamored with the power of science, often turn to genetic technology for easy answers to perplexing medical and social questions. This exaggerated perception is problematic. Genomic information can wield considerable influence, affecting the decisions of health care professionals, patients and their families, employers, in-

surers, and the justice system. How does society control this information without stifling the real potential for human good that it offers? The answer to this question must be in recognizing that trade-offs are inevitable. Permitting the Human Genome Initiative to proceed unabated will have costs in personal privacy. While careful security safeguards will not provide complete privacy, the public should be assured that genomic information will be treated in an orderly and respectful manner and that individual claims of control over those data will be adjudicated fairly.

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References

1. An expansive literature on genetic discrimination exists. See L. Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers," *American Journal of Law & Medicine*, XII (1991): 109-44; G.P. Smith and T.J. Burns, "Genetic Determinism or Genetic Discrimination," *Journal of Contemporary Health Law & Policy*, 11 (1994): 23-61; R.A. Epstein, "The Legal Regulation of Genetic Discrimination: Old Responses to New Technology," *Boston University Law Review*, 74 (1994): at 1-23; and M.A. Rothstein, "Discrimination Based on Genetic Information," *Jurimetrics*, 33 (1992): 13-18.
2. L.O. Gostin, "Health Information Privacy," *Cornell Law Review*, 80 (1995): 451-528.
3. See, for example, G.J. Annas, L.H. Glantz, and P.A. Roche, *The Genetic Privacy Act and Commentary* (Boston: Boston University School of Public Health, 1995); G.J. Annas, "Privacy Rules for DNA Databanks: Protecting Coded 'Future Diaries'," *JAMA*, 270 (1993): 2346-50; J.A. Kobrin, "Comment: Medical Privacy Issue: Confidentiality of Genetic Information," *UCLA Law Review*, 30 (1983): 1283-315; M. Powers, "Privacy and the Control of Genetic Information," in M.S. Frankel and A.S. Teich, eds., *The Genetic Frontier: Ethics, Law and Policy* (Washington, D.C.: American Association for the Advancement of Science Press, 1994): 77-100; and D.L. Burk, "DNA Identification Testing: Assessing the Threat to Privacy," *University of Toledo Law Review*, 24 (1992): 87-102.
4. Office of Technology Assessment, *Protecting Privacy in Computerized Medical Information* (Washington, D.C.: Government Printing Office, OTA-TCT-576, 1993); General Accounting Office, *Automated Medical Records: Leadership Needed to Expedite Standards Development* (Washington, D.C.: Government Printing Office, GAO/IMTEC-93-1, 1993); Task Force on Privacy, Department of Health and Human Services, *Health*

Records: Social Needs and Personal Privacy: Conference Proceedings (Washington, D.C.: DHHS, 1993); and Final Report of the Task Force on the Privacy of Private-Sector Health Records, Department of Health and Human Services (Washington, D.C.: DHHS, Sept. 1995).

5. Institute of Medicine, M.S. Donaldson and K.N. Lohr, eds., *Health Data in the Information Age: Use, Disclosure, and Privacy* (Washington, D.C.: National Academy of Sciences, 1994).

6. L.O. Gostin et al., "Privacy and Security of Personal Information in a New Health Care System," *JAMA*, 270 (1993): 2487-93.

7. P.T. Rowley, "Genetic Screening: Marvel or Menace?," *Science*, 225 (1984): 138-44.

8. *Id.*

9. B.S. Wilfond and K. Nolan, "National Policy Development for the Clinical Application of Genetic Diagnostic Techniques: Lessons from Cystic Fibrosis," *JAMA*, 270 (1993): 2948-54.

10. K. Savitsky et al., "A Single Ataxia Telangiectasia Gene with a Product Similar to PI-3 Kinase," *Science*, 268 (1995): 1749-53.

11. I.M. Olivos-Glander et al., "The Oculocerebrorenal Syndrome Gene Product is a 105kd Protein Localized to the Golgi Complex," *American Journal of Human Genetics*, 57 (1995): 817-23.

12. A.M. Goldstein et al., "Increased Risk of Pancreatic Cancer in Melanoma-Prone Kindreds with *p16^{INK4}* Mutations," *N. Engl. J. Med.*, 333 (1995): 970-74.

13. J.P. Struwing et al., "The Carrier Frequency of the BRCA1 185delAG Mutation is Approximately 1 Percent in Ashkenazi Jewish Individuals," *Nature Genetics*, 11 (1995): 198-200.

14. G. Kolata, "Tests to Assess Risks for Cancer Raising Questions," *New York Times*, Mar. 27, 1995, at A1; and E. Tanouye, "Gene Testing for Cancer to be Widely Available, Raising Thorny Questions," *Wall Street Journal*, Dec. 14, 1995, at B1.

15. L.B. Andrews and A.S. Jaeger, "The Human Genome Initiative and the Impact of Genetic Testing and Screening Technologies: Confidentiality of Genetic Information in the Workplace," *American Journal of Law & Medicine*, XVII (1991): 75-108; D. Orentlicher, "Genetic Screening by Employers," *JAMA*, 263 (1990): 1105, 1108; E.F. Canter, "Employment Discrimination Implications of Genetic Screening in the Workplace Under Title VII and the Rehabilitation Act," *American Journal of Law & Medicine*, 10 (1984): 323-47; K. Brokaw, "Genetic Screening in the Workplace and Employers' Liability," *Columbia Journal of Law & Social Problems*, 23 (1990): 317-46; and E.E. Schultz, "If You Use Firm's Counselors, Remember Your Secrets Could Be Used Against You," *Wall Street Journal*, May 26, 1994, at 1.

16. Gostin, *supra* note 1.

17. Report on the Task Force on Genetic Information and Insurance, *Genetic Information and Health Insurance* (NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, May 10, 1993); T.H. Murray, "Genetics and the Moral Mission of Health Insurance," *Hastings Center Report*, 22, no. 6 (1992): 12-17; and S. O'Hara, "The Use of Genetic Testing in the Health Insurance Industry: The Creation of a 'Biological Underclass'," *Southwestern University Law Review*, 22 (1993): 1211-28.

18. C. Ezzell, "Panel Oks DNA Fingerprints in Court Cases," *Science News*, 141 (1992): at 261; and G. Kolata, "Chief Says Panel Backs Courts' Use of a Genetic Test," *New York Times*, Apr. 15, 1992, at A1.

19. S.M. Suter, "Whose Genes Are These Anyway? Familial

Conflicts Over Access to Genetic Information," *Michigan Law Review*, 91 (1993): 1854-908.

20. W.E. Leary, "A Search for Lincoln's DNA," *New York Times*, Feb. 10, 1991, at 1.

21. H.R. 5612, Cong. 101, Sess. 2 (Sept. 13, 1990).

22. Gostin, *supra* note 2.

23. D. Brown, "Individual 'Genetic Privacy' Seen as Threatened; Officials Say Explosion of Scientific Knowledge Could Lead to Misuse of Information," *Washington Post*, Oct. 20, 1991, at A6 (quoting J.D. Watson as saying: "The idea that there will be a huge data bank of genetic information on millions of people is repulsive.").

24. E.W. Clayton et al., "Informed Consent for Genetic Research on Stored Tissue Samples," *JAMA*, 274 (1995): 1786-92.

25. P.R. Reilly, letter, "DNA Banking," *American Journal of Human Genetics*, 51 (1992): at 32-33.

26. *Id.*

27. Deputy Secretary of Defense Memorandum No. 47803 (Dec. 16, 1991).

28. E.D. Shapiro and M.L. Weinberg, "DNA Data Banking: The Dangerous Erosion of Privacy," *Cleveland State Law Review*, 38 (1990): 455-86 (many states authorize the banking of DNA usually for convicted sex offenders; the FBI is establishing a computerized DNA data bank); Burk, *supra* note 3; and Note, "The Advent of DNA Databanks: Implications for Information Privacy," *American Journal of Law & Medicine*, XVI (1990): 381-98.

29. Suter, *supra* note 19.

30. J.E. McEwen and P.R. Reilly, "Stored Guthrie Cards as DNA 'Banks'," *American Journal of Human Genetics*, 55 (1994): 196-200.

31. *Id.*

32. Department of Health and Human Services, *National Health and Nutrition Examination Survey III* (1994).

33. D. Nelkin and S. Lindee, *The DNA Mystique: The Gene as a Cultural Icon* (New York: W.H. Freeman, 1995); D. Nelkin, "The Double-Edged Helix," *New York Times*, Feb. 4, 1994, at A23; and R. Weiss, "Are We More Than the Sum of Our Genes?," *Washington Post Health*, Oct. 3, 1995, at 10.

34. N. Foster, "The Cystic Fibrosis Gene: Medical and Social Implication for Heterozygote Detection," *JAMA*, 263 (1990): 2777-83.

35. P. Reilly, "Rights, Privacy, and Genetic Screening," *Yale Journal of Biology & Medicine*, 64 (1991): 43-45.

36. N.A. Wivel and L. Walters, "Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives," *Science*, 262 (1993): 533-38.

37. P.J. Hilts, "Gene Transfers Offer New Hope for Interspecies Organ Transplants," *New York Times*, Oct. 19, 1993, at A1.

38. Struewing et al., *supra* note 13.

39. Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Toronto: Ontario Premier's Commission, 1992); and Shapiro and Weinberg, *supra* note 28. Later, I show why enacting genetic-specific privacy statutes, instead of a general statute applicable to all health information, may be problematic. This is not intended to undercut the observation that genomic data present distinct privacy concerns. Rather, I argue, that robust privacy legislation should cover all kinds of health information without creating "super" privacy protection for any particular kind of data, whether it be genomic data or data relating to STDs, HIV infection, mental health, or substance abuse.

40. Annas, *supra* note 3.

41. R.T. King Jr., "Soon, a Chip Will Test Blood for Diseases," *Wall Street Journal*, Oct. 25, 1994, at B1.

42. S.F. Kreimer, "Sunlight, Secrets, and Scarlet Letters: The

Tension Between Privacy and Disclosure in Constitutional Law," *University Pennsylvania Law Review*, 140 (1991): 1-147; R.C. Turkington, "Legacy of the Warren and Brandeis Article: The Emerging Unencumbered Constitutional Right to Informational Privacy," *Northern Illinois University Law Review*, 10 (1990): 479-520; and F.S. Chlapowski, Note, "The Constitutional Protection of Informational Privacy," *Boston University Law Review*, 71 (1991): 133-60.

43. *Webster v. Reproductive Health Servs.*, 492 U.S. 490 (1989); *Bowers v. Hardwick*, 478 U.S. 186 (1986); and *Paul v. Davis*, 424 U.S. 693 (1976).

44. *Whalen v. Roe*, 429 U.S. 589 (1977). See *Nixon v. Administrator of General Servs.*, 433 U.S. 425 (1977).

45. 429 U.S. at 605.

46. *Id.*

47. *Id.*

48. *Rasmussen v. South Fla. Blood Serv., Inc.*, 500 So. 2d 533 (Fla. 1987).

49. *U.S. v. Westinghouse Electric Corp.*, 638 F.2d 570 (3d Cir. 1980).

50. Gostin, *supra* note 2, at 499-508.

51. Workgroup for Electronic Data Interchange, *Obstacles to EDI in the Current Health Care Infrastructure* (Washington, D.C.: DHHS, 1992): app. 4, at iii.

52. H.R. 5612, Cong. 101, Sess. 2, 101 (Sept. 13, 1990) ("a bill to safeguard individual privacy of genetic information"). The bill provides individuals with certain safeguards against the invasion of personal genetic privacy by requiring agencies, *inter alia*, to permit individuals to determine what personal records are collected and stored; to prevent personal records from being used or disclosed with consent; to gain access to personal records; and to ensure accuracy of records.

53. Hereditary Disorders Act, Cal. Health & Safety Code § 151 (West Ann. 1990) (test results and personal information from the hereditary disorders programs are considered confidential medical records and can only be released with informed consent); Fla. Stat. Ann. § 760.40 (West Supp. 1994) (genomic data are the exclusive property of the person tested, are confidential, and may not be disclosed without the person's consent; genomic data collected for purposes of criminal prosecution, determination of paternity, and from persons convicted of certain offenses are exempted from confidentiality requirement); Me. Rev. Stat. Ann. tit. 22, § 42 (Supp. 1995) (personal medical information obtained in state's public health activities, including but not limited to genetic information, is confidential and not open to public inspection); Mass. Gen. Laws Ann. ch. 76, § 15B (West 1982) (data from state voluntary screening program for sickle cell, or other genetically linked diseases determined by the commissioner, are confidential); Mo. Ann. Stat. § 191.323 (Vernon Supp. 1996) (authorizing the health department to maintain a central registry for genomic information, and providing that identifying information is confidential); Oh. Rev. Code Ann. tit. XXXVII, § 3729.46 (Baldwin 1994) (health department and contractors must keep personal information, including genetic information, confidential); Tenn. Code Ann. § 68-5-504 (1992) (requiring health department to develop statewide genetic and metabolic screening programs including PKU and hypothyroidism, and requiring that the program follow state laws governing confidentiality); Va. Code § 32.1-69 (1950) (records maintained as part of genetic screening program are confidential except with informed consent); Ga. Code Ann. § 33-54-3 (Supp. 1995) (use of genomic information is authorized in criminal investigations and prosecutions, and scientific research); Kan. Stat. Ann. § 65-1, 106 (1994) (sickle cell testing information is confidential); 1995 Or. Laws 680 (requires informed consent

for the procurement of genetic information, and provides that an individual's genetic information is the property of the individual); 1995 La. Acts 11299.6; and Pa. S. 1774 (1993).

54. In Pennsylvania, see Genetic Information Confidentiality Act, Pa. S. 1774 (1993). In New York, see A. 5796, N.Y. Reg. Sess. (1995-96); S. 4293, N.Y. Reg. Sess. (1995); and S. 3118, N.Y. Reg. Sess. (1995).

55. Cal. Health & Safety Code § 151 (West Ann. 1990); Colo. Rev. Stat. 10-3-1104.7 (1994); Fla. Stat. Ann. § 760.40 (West Supp. 1994); Ga. Code Ann. § 33-54-3 (Supp. 1995); Kan. Stat. Ann. § 65-1, 106 (1994) (sickle cell only); 1995 Minn. Laws 251; 1995 N.H. Laws 101; and 1995 Or. Laws 680.

56. For example, Colo. Rev. Stat. 10-3-1104.7 (1994); Ga. Code Ann. § 33-54-3 (Supp. 1995); and Cal. Ins. Code § 10148 (West 1994).

57. For example, Colo. Rev. Stat. §§ 19-1-121, 25-1-122.5

(1995).

58. Nev. Rev. Stat. 396.525 (1991).

59. National Society of Genetic Counselors, *Resolutions* (rev. Nov. 1994).

60. Annas, Glantz, and Roche, *supra* note 3.

61. Gostin, *supra* note 2, at 513-27. Other work on public health information privacy is currently being done under the auspices of the CDC and the Carter Presidential Center.

62. The Medical Records Confidentiality Act, S. 1360, Cong. 104, Sess. 1 (1995), is pending. This statute would create a set of fair information practices for a wide range of health information.

63. In deriving these standards, the author appreciates the work of Professor Robert Weir of the National Human Genome Project and Joan Porter of the Office of Protection from Research Risks of the National Institutes of Health.